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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,061	03/02/2004	Jaime Simon	42801C	2855
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/791,061

Applicant(s)

SIMON ET AL.

Examiner

ABIGAIL FISHER

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The examiner for your application in the USPTO has changed. Examiner Abigail Fisher can be reached at 571-270-3502.

Receipt of Amendments/Remarks filed on October 3 2009 is acknowledged. Claims 1 and 3-5 were amended. Claims 1-5 are pending.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/892374 and 09091998, filed 6/26/01 and 06/23/98 respectively. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the

application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge

under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Withdrawn Rejections

The rejection of claims 1-5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in light of applicants' argument filed on October 3 2008.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 5 provides for the use of a water-soluble polyether glycol polymer, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 5 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35

U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, because while the claims provide for the "use" of water-soluble polyether glycol, the claims do not set forth any steps involved in the method/process, and thus it is unclear what method/process they are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Response to Arguments

Applicants argue that claim 5 is a use claim and the use is clearly defined as being an agent for the reduction of phosphate or oxalate in an animal.

Applicants' arguments filed October 3 2008 have been fully considered but they are not persuasive.

While applicants are correct that the claim states that the use of water-soluble polyether glycol for decreasing absorption of phosphate or oxalate from the gastrointestinal tract in an animal, there are no steps recited in the claim. Therefore it is unclear what method/process the claim is intending to encompass. In order to conform to US practice the claim must recite a step.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Modified Rejection Based on amendments in the reply filed on October 3 2008

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (US Patent No. 3320317, cited on PTO Form 1449) in view of WO/95/05184 (WO '184, cited on PTO Form 1449).

Applicant Claims

The instant application claims a method for decreasing the absorption of phosphate or oxalate from the gastrointestinal tract which comprises the steps of administering an effective amount of a formulation comprising a water-soluble polyether glycol polymer.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Rogers et al teach the quaternary ammonium adduct of polyepichlorohydrin (title, column 1 lines 12-25).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Rogers et al. do not teach that the quaternary ammonium adduct of polyepichlorohydrin can be utilized to decrease the absorption of phosphate or oxalate from the gastrointestinal tract. However, this deficiency is cured by WO '184.

WO '184 teaches the removal of phosphate with phosphate binding polymers by oral administration (abstract). Quaternary amines are disclosed (page 4 lines 8-14).

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill to use the polymer of Rogers et al to achieve the beneficial effect of phosphate removal in view of the teaching of WO '184 that polymers possessing quaternary amine moieties are effective for such removal.

As to the time of administration and amount of polymer administered, an optimum suitable time and amount can be obtained by routine experimentation.

Response to Arguments

Applicants argue that (1) Rogers does not teach or suggest administering an effective amount of polyepichlorohydrin derivatives to an animal in order to decrease absorption of phosphate and oxalate from the gastrointestinal tract. Applicants argue that (2) it would be very risky to even try to administer the polyepichlorohydrin material to an animal based on the teachings of Rogers because Rogers does not suggest they would be suitable for administering to animals. Applicants argue that (3) WO '184 does

not teach the polymers of the instant invention. Applicants argue that (4) neither Rogers nor WO '184 teach removal of oxalates.

Applicants' arguments filed October 3 2008 have been fully considered but they are not persuasive.

Regarding applicants' first argument, while Rogers does not specify that the polymers of the invention can be utilized to decrease absorption of phosphate and oxalate from the gastrointestinal tract that is why WO '184 is relied upon. The polymers of Rogers are made from epichlorohydrin and allylamine. The polymers of WO '184 are also made from monomers of epichlorohydrin and allylamine (see column 5 and paragraph 2 of column 8). WO '184 teaches specifically that this polymer is useful in binding phosphate thereby reducing its absorption from the GI tract. The method of removing is achieved via ion exchange. Therefore, based on the teachings of WO '184 of substantially similar polymers one of ordinary skill in the art would have a reasonable expectation that the polymers of Rogers would additionally be suitable for binding phosphate and decreasing its absorption from the GI tract.

Regarding applicants' second argument, as indicated above the polymers of WO '184 are made from the same monomers and these polymers are administered to animals. Therefore, there is a reasonable expectation that the polymers of Rogers would additionally be suitable for administration to animals. Furthermore, applicants have provided no evidence that they cannot be administered to animals. "The arguments of counsel cannot take the place of evidence in the record." *In re Schulze*, 346 F.2d 600, 145 USPQ 716, 718 (CCPA 1965), *In re Huang*, 40 USPQ 2d 1685 (Fed.

Cir. 1996), *In re De Blauwe et al.*, 222 USPQ 191, (Fed. Cir. 1984). Applicant has not proved any factual evidence establishing unobviousness.

Regarding applicants' third argument, as indicated above WO '184 teach polymers comprising monomers which are the same as those taught in Rogers and that these polymers can be utilized to bind phosphate via ion exchange. Furthermore, the polymers of WO '184 comprise epichlorohydrin which is the same polyether glycol polymer claimed.

Regarding applicants' fourth argument, the polymers of WO '184 bind phosphate via ion exchange. Since phosphates are negative ions and oxalates are negative ions as well, there is a reasonable expectation that the polymers would reasonably bind other negative ions via ion exchange as that is the primary purpose of ion exchange resins. Furthermore, as evidenced by Laker et al. (Journal of Pharmaceutical Sciences 1981) absorption of oxalate can be decreased either by binding via ion exchange resins or by binding bile acids which necessarily decrease the absorption of oxalates (page 1065, second and third paragraphs). Therefore, since oxalates can bind ion exchange one of ordinary skill in the art would expect that the polymer would bind oxalate as well.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616